REMARKS

In the April 6, 2005, first Office Action in this application, the United States Patent and Trademark Office (hereinafter "the Office") rejected Claims 1-6, 10, 12, 16, 20, and 25-29 under 35 U.S.C. § 102(b) as being anticipated by the teachings of U.S. Patent No. 5,867,821, issued to Ballantyne et al. (hereinafter "Ballantyne et al."). Claims 7 and 8 were rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of Ballantyne et al. Claim 9 was rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of Ballantyne et al. and further in view of the teachings of U.S. Patent No. 6,558,320, issued to Causey III et al. (hereinafter "Causey et al."). Claims 11, 13, 18, 19, 30, and 31 were rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of Ballantyne et al. and further in view of the teachings of U.S. Patent No. 5,671,282, issued to Wolff et al. (hereinafter "Wolff et al."). Claims 14, 15, 32, and 33 were rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of Ballantyne et al., Wolff et al., and further in view of the teachings of U.S. Patent No. 6,016,476, issued to Maes et al. (hereinafter "Maes et al."). Claims 17 and 34 were rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of Ballantyne et al. and further in view of the teachings of U.S. Patent No. 6,289,316, issued to Aghili et al. (hereinafter "Aghili et al."). Claims 21-24, 35, and 36 were rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of Ballantyne et al. and further in view of the teachings of U.S. Patent No. 6,131,090, issued to Basso Jr. et al. (hereinafter "Basso et al."). Claim 37 was rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of Ballantyne et al., Basso et al., and further in view of the teachings of Maes et al.

Prior to discussing in detail why applicants believe that all of the claims in this application are allowable, a brief description of the applicants' invention and a brief description of the teachings of the cited and applied references are provided. The following background and the discussions of the disclosed embodiments of applicants' invention and the teachings in the

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cited and applied references are not provided to define the scope or interpretation of any of the claims of this application. Instead, such discussions are provided to help the Office to better appreciate important claim distinctions discussed thereafter.

Summary of the Claimed Invention

Applicants' claimed invention is directed to a device, a network, and a method for distributing and transferring medical records, pharmaceutical orders, stationary assessment, and information from a variety of medical sources including patient diagnosis in a mobile environment. A device form of the invention includes a hand-held mobile field device configured to provide wireless communication with a plurality of patient medical monitoring devices.

In accordance with further aspects of this invention, a network form of the invention comprises a network that includes at least one mobile field device configured to provide communication with a plurality of patient medical monitoring devices. The network is configured to aggregate and to make available to the mobile field unit a combination of manual, automated, fixed continuous and mobile patient monitoring and assessments.

In accordance with further aspects of this invention, another method form of the invention comprises a network that includes at least one mobile field device configured to provide communication with a plurality of patient medical monitoring devices. The network is electronically connected to databases maintained by a hospital.

In accordance with further aspects of this invention, a further network form of the invention comprises a network that includes at least one mobile field device configured to provide communication with a plurality of patient medical monitoring devices. The network further comprises a central repository containing medical information and a plurality of subsystem databases linked to the central repository via at least one member of the group consisting of encryption software and secure hardware that tags transmissions and retrievals.

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In accordance with further aspects of this invention, an additional network form of the invention comprises a network that includes at least one mobile field device configured to provide communication with a plurality of patient medical monitoring devices. The network is configured to link a prescription drug order processing system with prescription data and secure patient documentation and health assessment.

In accordance with further aspects of this invention, a network form of the invention also comprises a network comprising a medical database, a secure medical database monitoring system communicatively coupled to the medical database, and a first data monitoring manager communicatively coupled to the secure medical database monitoring system. At least one of the secure medical database monitoring systems in the data monitoring manager is configured to provide controlled electronic access to the medical database by a plurality of entities in accordance with a specification provided by an authorized user. The network is configured to sequentially control said electronic access with respect to a patient's data so that at least a first predetermined entity must access the patient's data before a second predetermined entity is permitted access.

In accordance with further aspects of this invention, a method form of the invention comprises a method for communicating medical data comprising communicating medical data wirelessly to a hand-held mobile field unit from a plurality of patient medical monitoring devices and communicating the medical data received from the hand-held mobile field unit to a medical database via a secure network.

In accordance with further aspects of this invention, another method form of the invention comprises a method for controlling access to a medical database which includes defining an access protocol for entities accessing patient data including at least a first entity having initial access to the patient data. The method further includes permitting access to the

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patient data by the at least first entity and conditioning each further access to the patient data by additional entities upon prior access by at least one predetermined prior entity.

Summary of Ballantyne et al.

The system of Ballantyne et al. focuses on the distribution and administration of medical services, entertainment services, electronic medical records, educational information, and so on, to a patient's individual electronic patient care station (PCS) interconnected to a master library (ML), which stores data in digital compressed format. The patient's medical personnel interact with this medical information network through the PCS and receive the requested service or data from the ML. The data can be displayed either on an associated television set or video monitor or through wireless/IR communication to a peripheral personal data assistant.

Ballantyne et al. explains the PCS in greater detail as follows:

> Because the PCS utilizes a coaxial cable interface, the PCS can be located at the residence of the patient. This facilitates the out-sourcing of health care to external health care service providers. The PCS receives from the ML post recovery rehabilitation information in the form of video and text data, special dietary/nutrition instructional data, physical rehabilitation programming, etc. The PCS also interfaces with specific external health care monitoring equipment to register and track certain patient characteristics as temperature, pulse rate, etc., then pre-processes the data, and transmits the results back to the ML. Video monitoring of the patient's condition is also facilitated through the additional remote small video camera. By means of a PDA carried by an external care giver, detailed health record information is accessed from the ML and modified with up-to-date medical diagnostic data.
>
> . . .
>
> The PDA automatically transfers the modified health record or portions thereof to the PCS via the wireless/IR communications link (102).

See Ballantyne et al. at Col. 11, lines 12-27 and Col. 12, lines 35-37. In contrast, applicants' claimed invention recites a hand-held mobile field device configured to provide wireless communication with a plurality of patient medical monitoring devices. It is true that the PCS of

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the system of Ballantyne et al. interfaces with health care monitoring equipment but the PCS is not a hand-held mobile field device. The PDA of the system of Ballantyne et al. is arguably a mobile device, but it is not configured to provide wireless communication with a plurality of patient medical monitoring devices. Instead, the PDA of Ballantyne et al. directly communicates with the PCS, which is not a patient medical monitoring device.

Ballantyne et al. also describes a security architecture that identifies and authenticates individuals requesting access to Ballantyne et al.'s health record database at Col. 7, line 66 to Col. 8, line 64:

> Initially, each potential user of the network has completed a questionnaire that identifies who they are and specific demographics about them. Once successfully completed, an [sic] unique identification number (ID) is assigned to each user and their personal profile data is stored electronically online. Users are subdivided into specific categories relative to their qualifications, their professional status, and their necessity to gain access to medical information and/or the medical information network, i.e., physicians as compared to nursing staff, ambulance personnel as compared to medical staff, surgeons as compared to psychiatrists, etc. To gain access to the medical information network, each user first enters their ID number (322). This ID number is then validated (324) with a central user list to confirm they are a legitimate user. If a match does not occur they are immediately denied system access (326). However, if a match is determined, the users [sic] personal electronic profile is accessed (328). The system then queries (330) the user with a specific question (332), i.e., What was your mother's name? If the user answers correctly (334), access to the network is granted (336) and the time of access is logged (344). This completes the user identification and authentication process.

One of the differences between applicants' claimed invention and the system of Ballantyne et al. is that Ballantyne et al. is unable to sequentially control access to a patient's data where a first entity must access the patient's data before a second entity is permitted to access.

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Summary of Causey et al.

The system of Causey et al. is directed to a system that includes a hand-held data assistant (PDA 10). The PDA is in communication with a telemetered characteristic monitor transmitter 100 coupled to a sensor set 150. The PDA is also in communication with an infusion pump 400 connected to an infusion set 450. See Figure 7. The sensor set detects and/or quantifies specific agents or compositions in a patient's blood and communicates such findings to the telemetered characteristic monitor transmitter, which then communicates to the PDA. The infusion pump 400 is not a monitor like the telemetered characteristic monitor transmitter 100 but instead acts to adjust a treatment regimen, which typically includes the regular administration of insulin to the patient.

Summary of Wolff et al.

The system of Wolff et al. is directed to a document processing system in which a server subsystem stores information corresponding to a document containing human-readable and machine-readable information, and a client subsystem that receives the document and interprets the machine-readable information. The client subsystem contacts the server to verify validity of information in the document using a communications network that allows information to be exchanged between the server and a client.

Summary of Maes et al.

The system of Maes et al. is directed to a personal digital assistant that has a local mode of operation which is performed by providing the PDA with biometric data and selecting one of the pre-enrolled credit cards that are stored on the PDA. Upon biometric verification, a smart card is written with the selected card information, which is then used to initiate a consumer transaction. In the absence of an unexpired digital certificate, however, the selected card information will not be written to the smart card notwithstanding that the user may have passed local biometric verification.

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Summary of Aghili et al.

The system of Aghili et al. is directed to a database format, which is unalterable, for creating progress notes in a patient's medical record. New versions of the notes that reflect revised viewpoints of the user may be created without deleting original notes. The database which stores these progress notes can check accuracy in diagnosis and orders by the user.

Summary of Basso et al.

The system of Basso et al. is directed to controlled access to information stored on a smart card.

The Claims Distinguished

The Office has failed to show, and applicants are unable to find, where any of the cited and applied references, either alone or in combination, disclose the subject matter of the claimed invention. For example, none of the applied and cited references teaches "a hand-held mobile field device configured to provide wireless communication with a plurality of patient medical monitoring devices," as recited in Claim 1. The Office indicated that this limitation is taught by Ballantyne et al. at Col. 11, lines 18-21, and Col. 12, lines 35-37, which disclose the following:

> The PCS also interfaces with specific external health care monitoring equipment to register and track certain patient characteristics as temperature, pulse rate, etc., then pre-processes the data, and transmits the results back to the ML.
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> . . .
>
> The PDA automatically transfers the modified health record or portions thereof to the PCS via the wireless/IR communications link (102).

That particular portion of Ballantyne et al. has nothing to do with the claimed limitation. The Office indicated that the PDA of Ballantyne et al. provides wireless communication with patient monitoring devices. That is incorrect. The PDA of Ballantyne et al. does not interface with a plurality of patient medical monitoring devices. It is the PCS of Ballantyne et al., but the

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problem is that the PCS is not a hand-held mobile field device. The Office attempted to liken the PCS of Ballantyne et al. with patient monitoring devices. But this is not correct. Consequently, the Office has failed to state a *prima facie* case of anticipation.

As a second example, none of the applied and cited references teaches "a network including at least one mobile field device configured to provide communication with a plurality of patient medical monitoring devices, the network being configured to aggregate and to make available to the mobile field unit a combination of manual, automated, fixed continuous and mobile patient monitoring and assessments," as recited in Claim 5. The system of Ballantyne et al. does use a PDA, but the PDA does not communicate with a plurality of patient medical monitoring devices; and its PCS, which interfaces with health care monitoring equipment, is not a mobile field device. Thus, the Office has failed to state a *prima facie* case of anticipation.

As a third example, among other differences, none of the applied and cited references teaches "a network including at least one mobile field device configured to provide communication with a plurality of patient medical monitoring devices, and the network electronically connected to databases maintained by a hospital," as recited in Claim 6. The PCS of Ballantyne et al. interfaces with health care monitoring equipment but is not a mobile field device, and Ballantyne et al.'s PDA is not configured to provide communication with a plurality of patient medical monitoring devices. Therefore, another *prima facie* case of anticipation has not been established by the Office.

As a fourth example, applicants are unable to find, and the Office has failed to show, where the applied and cited references teach "a network including at least one mobile field device configured to provide communication with a plurality of patient medical monitoring devices, the network further comprising a central repository containing medical information and a plurality of subsystem databases linked to the central repository via at least one member of the group consisting of encryption software and secure hardware that tags transmissions and

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retrievals," as recited in Claim 12. No mobile field device that is configured to provide communication with a plurality of patient medical monitoring devices is disclosed by Ballantyne et al. The PCS of Ballantyne et al. is not a mobile field device and the PDA of Ballantyne et al. does not communicate with a plurality of patient medical monitoring devices. Thus, the Office has continued to fail to state a *prima facie* case of anticipation.

As a fifth example, applicants are unable to find, and the Office has failed to show, where the applied and cited references, alone or in combination, teach "a method for communicating medical data comprising communicating medical data wirelessly to a hand-held mobile field unit from a plurality of patient medical monitoring devices, and communicating the medical data received from the hand-held mobile field unit to a medical database via a secure network," as recited in Claim 25. The health care monitoring equipment of Ballantyne et al. does not communicate to the PDA, but instead to the PCS, which is not a hand-held mobile field unit. Thus, the Office has not been able to establish a *prima facie* case of anticipation.

As the sixth example, none of the applied and cited references teaches "a network including at least one mobile field device configured to provide communication with a plurality of patient medical monitoring devices, the network configured to link a prescription drug order processing system with prescription data and secure patient documentation and health assessment, as recited in Claim 18. Ballantyne et al.'s PCS is not a mobile field device and its PDA does not communicate with a plurality of patient medical monitoring devices. The PDA of Ballantyne et al. communicates with a PCS, but the PCS is not a patient medical monitoring device. Given the defects of Ballantyne et al., the Office has sought to combine Ballantyne et al. with Wolff et al., which combination applicants specifically deny. Wolff discloses a system for document verification and tracking and has nothing to do with the limitation "a network including at least one mobile field device configured to provide communication with a plurality of patient medical monitoring devices." Given the defects of Ballantyne et al. and Wolff et al.,

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there is no reason for their combination and the Office has failed to state a *prima facie* case of obviousness.

As a seventh example, none of the cited and applied references teaches "network is configured to sequentially control said electronic access with respect to a patient's data so that at least a first predetermined entity must access the patient's data before a second predetermined entity is permitted access" as recited in Claim 20. As an eighth example, applicants are unable to find, and the Office has failed to show, where the applied and cited references teach "conditioning each further access to the patient data by additional entities upon prior access by at least one predetermined prior entity" as recited in Claim 35.

The Office has recognized that Ballantyne et al. has failed to teach the recited claimed limitations with reference to Claims 1, 5, 12, 18, 20, and 25. Given the defects of Ballantyne et al., the Office has sought to combine that reference with Basso et al., which combination applicants specifically deny. The Office has opined that the claim limitations can be found at Col. 9, lines 44-46, and Col. 14, lines 42-49, of Basso et al.:

> In other embodiments access session information can include information such as ID(H), ID(P), or an access sequence number which uniquely identifies each access session.
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> . . .
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> For example, the head of an emergency medical service might have authority to access such sensitive, critical data in the event of a system failure while other medical personal [*sic*] could only access such data with an access code issued by a Trusted Authority, but without needing immediate access to the Trusted Authority. Of course, non-sensitive information, such as blood type, can simply be printed on the face of the card.

It is a mystery what those portions of Basso et al. have anything to do with the claimed limitations. One claimed limitation requires that "a first predetermined entity must access the patient's data before a second predetermined entity is permitted access." In the example provided

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by Basso et al., if other medical personnel were to obtain an access code issued by the Trusted Authority, the medical personnel could access, at the same time as the head of the emergency medical service, sensitive, critical data in the event of a system failure. There is no control that requires a first entity to access a patient's data before a second entity is permitted access. The system that is disclosed by Basso et al. is nothing more than a conventional authentication mechanism and it has nothing to do with the claimed invention. Given the defects of Ballantyne et al. and Basso et al., there is no advantage to combining them, and subsequently the Office has failed to state a *prima facie* case of obviousness.

Given the defects of Ballantyne et al., the Office has attempted to combine Ballantyne et al. with a number of references, all of which combinations applicants specifically deny. For example, the Office has sought to combine Ballantyne et al. and Causey et al., but because Causey et al. does not disclose a mobile field device configured to provide communication with a plurality of patient medical monitoring devices, it cannot cure the defects of Ballantyne et al. As previously discussed, the combination of Ballantyne et al. and Wolff et al. is defective and the Office has sought to combine that defective combination with Maes et al. Maes et al. also fails to disclose a mobile field device configured to provide communication with a plurality of patient medical monitoring devices and subsequently Maes et al. cannot cure the defects of Ballantyne et al. and Wolff et al. The Office has also sought to combine Ballantyne et al. and Aghili et al., but Aghili et al. also does not disclose or suggest a mobile field device configured to provide communication with a plurality of patient medical monitoring devices, and thus, Aghili et al. cannot cure the defects of Ballantyne et al. Finally, the Office has tried to combine Maes et al. with the defective combination of Ballantyne et al. and Basso et al. Maes et al. does not teach or suggest "conditioning each further access to the patient data by additional entities upon prior access by at least one predetermined prior entity" as recited in Claim 35. Subsequently, Maes

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et al. cannot cure the defects of Ballantyne et al. and Basso et al. and there is no reason for their combination.

Because the Office has failed to state a *prima facie* case of anticipation or obviousness, the rejections should be withdrawn. Independent Claims 1, 5, 6, 12, 18, 20, 25, and 35 are clearly and patentably distinguishable over the cited and applied references. Claims 2-4, 7-11, 13-17, 19, 22-24, 26-34, and 36-37 are allowable because they depend from allowable independent claims and because of the additional limitations added by those claims. Consequently, reconsideration and allowance of Claims 1-20 and 22-37 is respectfully requested.

Respectfully submitted,

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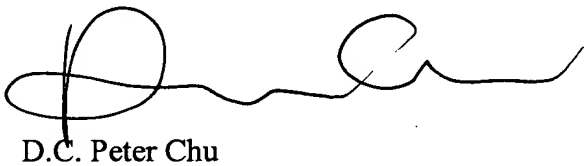

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